DEC 2 1 2011

Section 6 510(k) Summary
Fukuda Denshi VaSera VS-1500AU

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR part 870.92.

The assigned 510(k) number is: K112521.

1. **Submitter:**

Fukuda Denshi U.S.A. INC.
17725 NE 65th St. Building C
Redmond WA, 98052
Tel: 425-881-7737
Fax: 425-869-2018

- **Contact Person:**

Doug Blakely
Director- Regulatory Affairs
Fukuda Denshi U.S.A. INC.
17725 NE 65th St. Building C
Redmond WA, 98052
Tel: 425-881-7737
Fax: 425-869-2018
Email: DBlakely@fukuda.com

- **Date Prepared:** **August 15, 2011**

2. **Device Name:**

- **Proprietary Name:** Fukuda Denshi VaSera Model VS-1500AU

- **Common Name** Noninvasive blood pressure measurement system and Vascular profiling system

- **Classification**

DXN Noninvasive blood pressure measurement system
DQC Phonocardiograph
JOO Heart Sound Transducer

The following device classifications apply to this device:

Names:	Class:	CFR:
Non-invasive Blood Pressure Monitor	II	870.1130
Phonocardiograph	I	870.2390
Heart sound Transducer	II	870.2860

All of these devices are reviewed by the Cardiovascular Devices Panel

510(k) Summary
Fukuda Denshi VaSera VS-1500AU

Legally Marketed Predicate Devices:

Colin Medical VP-1000/2000 (K013434)
Fukuda Denshi DS-5300 Patient Monitor (K964187)

Description:

The Fukuda Denshi VaSera model VS-1500AU is a prescriptive device intended for use by health care professionals. It is designed to be used to assist the clinician in the detection of peripheral vascular diseases and has been designed and tested to automate published clinical diagnostic test methods. The device is capable of measuring non-invasive blood pressures, non-invasive pulse volume recordings and heart sounds. In addition, the device is capable of calculating specific clinically recognized indices such as ABI (Ankle Brachial Index), TBI (Toe Brachial Index) and pulse wave velocity.

Statement of Intended Use:

The Fukuda Denshi VaSera model VS-1500AU is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases. It has a capability of measuring non-invasive blood pressures, heart rate, pulse volume recordings and heart sounds.

The device also has the capability of calculating ABI (Ankle Brachial Index), TBI (Toe Brachial Index), and pulse wave velocity measurements.

The device is intended to be used under the order of a physician, in hospitals, doctor's offices, clinics or other medical facilities where non-invasive peripheral vascular tests are performed.

The device is intended to be used on adult population only.

The device is not intended for home use.

Technological Characteristics and Substantial Equivalence:

The Fukuda Denshi Vasera Model 1500AU incorporates similar non-invasive technology as the predicate devices. The device uses the same technology as the Colin Medical VP-1000/2000 (K013434) for assessing lower extremity peripheral pressures and calculated indices such as Ankle-Brachial Index, Toe-Brachial Index and PWV values. The device also uses the same standard NIBP module as the Fukuda Denshi DS-5300 Patient Monitor (K964187) for assessing upper brachial blood pressures.

The device provides a means for interfacing with the patient, collecting specific physiological data, processing the data and generating a report of specific standard vascular indices to assist the clinician in the detection of peripheral vascular diseases.

The technological characteristics of the Vasera Model 1500AU do not affect the safety or efficacy of the device. Any safety issued raised by this software controlled medical device are wither the same issues already addressed by the predicate devices or are addressed by the Risk Management Report (See Exhibit 4.1) or in the system validation.

Testing: The Fukuda Denshi VaSera model VS-1500AU has been subjected to extensive safety, environmental and performance testing.
Final testing for the device included various performance tests, including clinical validation using the predicate device, to insure that all functional and performance specifications were met.

The Fukuda Denshi VaSera model VS-1500AU has also been tested to assure compliance to the requirement of various published standards including the following:

UL60601-1; 2006,
IEC 60601-1 :1988+A1+A2
IEC 60601-1-1 Ed. 2.0 :2000
IEC 60601-1-1 Ed. 2.0 :2001+Am1 :2004
IEC 60601-1-4 Ed. 1.1 :2000

Conclusion: In conclusion, drawing from laboratory testing, validation and risk Analysis, the Fukuda Denshi VaSera model VS-1500AU demonstrates that this device is as safe and effective and performs as well as the legally marketed predicate devices, the Colin Medical VP-1000/2000 (K013434) and the Fukuda Denshi DS-5300 Patient Monitor (K964187).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

Fukuda Denshi USA, Inc.
c/o Mr. Doug Blakely
Director, Regulatory Affairs
17725 NE 65th Street, Building C
Redmond, WA 98052-4911

Re: K112521
Trade/Device Name: Fukuda Denshi Vasera Model VS-1500AU
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: II (two)
Product Codes: DXN, DQC, JOO
Dated: November 29, 2011
Received: December 2, 2011

Dear Mr. Blakely:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112521

Device Name: **Fukuda Denshi Vasera Model 1500AU**

Indications For Use:

The Fukuda Denshi VaSera model VS-1500AU is a non-invasive diagnostic system designed to assist in the detection of peripheral vascular diseases. It has a capability of measuring non-invasive blood pressures, heart rate, pulse volume recordings and heart sounds.

The device also has the capability of calculating ABI (Ankle Brachial Index), TBI (Toe Brachial Index), and pulse wave velocity measurements.

The device is intended to be used under the order of a physician, in hospitals, doctor's offices, clinics or other medical facilities where non-invasive peripheral vascular tests are performed.

The device is intended to be used on adult population only.

The device is not intended for home use.

Prescription Use X AND/OR
Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112521